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Comparison of the effects of three methods used in the treatment of tubal ectopic pregnancy on tubal patency

Treatment methods for tubal ectopic pregnancy

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Abstract

Aim: We aimed to compare the three methods used in the treatment of tubal ectopic pregnancy to the effects of tubal patency with hysterosalpingography. This study aims to evaluate the use of methotrexate therapy, surgery, and expectant supervision in the assessment of risks and benefits of the characteristics of individual patients.

Materials and Methods: In our clinic between January 2009- May 2015, 60 patients who were diagnosed with tubal ectopic pregnancy and had treatment and also have no history of previous ectopic pregnancy and tubal surgery enrolled in our study. The first group received treatment with methotrexate, the second group received laparoscopic salpingostomy and the third group received laparotomy which is made tubo-tubal anastomosis with a catheter after the resection of the ectopic pregnancy. The patients without an ipsilateral tubal passage were treated with diagnostic laparoscopy. Data were analyzed using descriptive statistical methods (mean, standard deviation, frequency) quantitative data, and the Mann-Whitney U test. Fisher's Exact Chi-square test was used to compare the qualitative data. The significance was evaluated as a <0.05 level.

Results: Tubal patency cannot be observed for 5 out of 20 (25%) patients in the MTX group, 4 out of 20 (20%) patients in the salpingostomy group, 1 out of 20 patients (5%)in the anastomosis group.

Discussion: When tubal patency was evaluated for all 3 groups no statistically significant difference was seen (p> 0.05) between the MTX group and salpingotomy groups in terms of tubal patency. But after treatment of anastomosis group tubal patency was monitored statistically significant (p <0.05).

Keywords

Tubal Ectopic Pregnancy, Laparoscopic Salpingostomy, Methotrexate, Tubo-Tubal Anastomosis, Tubal Patency

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Introduction

Ectopic pregnancy is described as an instance in which the ovum is fertilized but fails to implant in the cavity of the uterus, rather the fallopian tubes are the most common site for such an occurrence. It may also occur at the tubal, interstitial, ovarian, cervical, abdominal, intraligamentary, or heterotopic sites. Nevertheless, it occurs more often in the ampullar part of the fallopian tubes. The incidence of ectopic pregnancy is roughly estimated to be around 2% of all pregnancies. In the last few decades, an increasing trend in the instances of ectopic pregnancies has been noted. This upsurge is mainly due to the increased rates of pelvic infections, the increase in the number of intrauterine device users, and the increase in the use of surgical procedures for the treatment of infertility [1, 2].

Ectopic pregnancy is diagnosed through integrating obstetric history, gynecological and physical history, ultrasound examination, determination of the beta-hCG levels in serum, culdocentesis, D&C, and laparoscopy. Methotrexate (MTX) therapy is commonly used in the treatment of ectopic pregnancy, but it needs proper characterization of the clinical features as well as the rate of success [3, 4]. Medical, surgical, and expectant management can all be employed in the management of ectopic pregnancy, and all methods appear to be effective. Effective treatment options are guided by the clinical conditions, the site of the ectopic pregnancy, and the actual resources available. Both ectopic pregnancy and the treatment utilized have the potential of causing damage to the fallopian tubes which is a major risk factor in women who wish to conceive in the future [5, 6].

The objective of preparing this study is to evaluate and compare the effectiveness of three different methods of performing surgery for ectopic pregnancy on the patency of the fallopian tubes. This assessment will enable the evaluation of treatment options and their effect on the patency of fallopian tubes and subsequently, fertility available to the woman while minimizing chances of ectopic pregnancy. This study aims to evaluate the use of methotrexate therapy, surgery, and expectant supervision in the assessment of risks and benefits concerning the characteristics of individual patients.

Materials and Methods

The purpose of this study was to evaluate the tubal patency rates following the treatment of tubal ectopic pregnancies with methotrexate (MTX) laparoscopic salpingostomy or the catheter-assisted tubo-tubal anastomosis methods. The research was conducted retrospectively by reviewing the medical records of patients hospitalized with a diagnosis of tubal ectopic pregnancy between January 2009 and March 2015 at Necmettin Erbakan University, Meram Faculty of Medicine, Department of Obstetrics and Gynecology. Before the study commenced, clearance was obtained from the Necmettin Erbakan University Meram Faculty of Medicine Ethics Committee.

The inclusion criteria of the study were 60 patients aged between 20 and 44 years who never had contact with ectopic pregnancy or tubal surgery and who were recruited in this study. These women were subjected to hysterosalpingography(HSG) 6 months after treatment and if no ipsilateral tubal patency was observed, diagnostic laparoscopy was performed. For treatment of ectopic pregnancy patients were categorized into three groups of twenty each according to the management technique used: those who received strawberry Texas sisters; the salpingostomy group, including patients who ended up having laparoscopic salpingostomy; and the anastomosis group which included patients who had laparotomy and underwent catheter assisted tubo-tubal anastomosis. Women who had had salpingectomy, salpingotomy, or had heterotopic pregnancy were not included in the trial. These treatment approaches have been followed based on specific criteria (Table 4).

Women were chosen by looking backward at their records of gynecological history and examinations; β-hCG check-ups, transvaginal ultrasound, and D & C to verify tubal ectopic pregnancy. For those who were surgically operated on, the diagnosis of the disease was confirmed by histopathological examinations of the operated parts. For instance, in women who were administered MTX, the diagnosis was based on the absence of the chorionic villi in the D & C specimen, while there was a clear mass of ectopic pregnancy observable in the ultrasound outside the corpus luteum.

The age of the patients, the pre-treatment serum β-hCG levels, hemogram and liver and kidney function tests (LFT and KFT), the results of the TVUSG examination, the site of ectopic pregnancy, the size of the ectopic pregnancy if present, and the presence of fetal heart sounds were all documented for every patient.

The patients who received MTX treatment in a single-dose MTX protocol were included in this group. On Day 1, women received MTX at a dosage of 50mg/m². Only one patient was given MTX on Day 7 through an unplanned policy due to having a serum β-hCG decrease of less than 15%.

Laparoscopic salpingostomy is performed on hemodynamically stable women who have not yet ruptured tubal ectopic pregnancy. A linear cautery incision of a length of 2 cm was done on the antimesenteric border of the mass of ectopic pregnancy to permit the excision of the ectopic tissue. Hemostasis was achieved and the procedure was completed.

A combination of catheter-assisted and tubo-tubal anastomosis techniques was used in women with ruptured, hemodynamically unstable tubal ectopic pregnancies. The excised tube was a 20G epidural catheter at one of its ends through the medial portions of the upper Gonadal tubal and then towards its fundus end. The advancing lateral end of the upper Gonadal tubal pointed anteriorly and was fimbrial. The aligned sides of the upper Gonadal tubal were sutured with six zero Vicryl over the tip of the catheter insertion tube. The cut lateral end of the catheter that pointed anteriorly and fimbrial was guided through the abdominal wall and removed after forty-eight hours following the surgery.

In each of the 3 treatment groups, women who responded and benefited from the treatment were called after six months to have HSGs done after normalization of serum β-hCG levels. Women with the loss of opposite-sided tubal patency previously confirmed by HSG proceeded to diagnostic laparoscopy to confirm the passage of the methylene blue dye out of the cervical by looking at the tubes.

The clinical and demographic variables including the treatment

outcomes were assessed for the females who had the HSG and the diagnostic laparoscopes aimed at patency of the tubes.

Statistical Analysis

The verification of the findings of this study makes use of SPSS 16 Statistical Software as well as statistical analyses. For the analysis of the data, several descriptive statistical methods such as mean, standard deviation, and frequency were utilized. A Mann-Whitney U test was used for the comparison of quantitative variables. In the case of the comparison of qualitative variables, a Fisher's Exact Chi-Square test was used. Statistical significance was set at the $p<0.05$ level.

Ethical Approval

This study was approved by the Ethics Committee of Necmettin Erbakan University, Meram Faculty of Medicine (Date: 2015-03-15, No: 2015/223).

Results

Patients aged between 20 and 44 years with sixty patients in the study are the focal point. Three groups were formed based on the treatment applied to the twenty patients: MTX, L/S, and L/P. In particular, the study spanned from January 2009 until March 2015.

The average age of the MTX group was 30.90 years, the salpingostomy group aged 28.75 years and below, and the anastomosis group had an average age of 30.90. Across the three treatments, the average age difference was insignificant. The participants enrolled in the MTX group had pre-treatment levels of β-hCG levels that varied in value between 244 to 7542 mIU/mL with a mean of 2287±1735 mIU/mL. Except for a single participant who received a second dose, all participants in the MTX group were treated with a single MTX dose. β- hCG of the salpingostomy group had endpoints of 360 to 15,810, with 7611.395±4615.53 as their average. For the anastomosis group minimum and maximum levels of β-hCG were 244 and 19,435 mIU/mL respectively while the mean value was 6468.25±5069.82 mIU/mL. Between the salpingostomy and anastomosis groups, they had pre-treatment β-hCG levels within the same range, however when compared to β-hCG levels in the MTX group, the levels were significantly lower as was statistically established with ($p<0.05$).

In terms of measurement using transvaginal ultrasonography (TVUSG), the ectopic pregnancy that was measured weighed within a range of 16.20±5.80 mm for the MTX group, 26.25±11.36 mm for the salpingostomy group and 28.89±4.84 mm for the anastomosis group. The range of sizes of the ectopic pregnancies as measured by ultrasonography differed across the three groups as the p-value was greater than 0.05.

The TTG obtained results for six patients who were confirmed to have prima-facie tubal patency, this was for the MTX group who showed HSG results of absence of ipsilateral tubal patency. During the procedures one of these six patients was revealed to have tubal patency and the other five did not hence, there were no tubal patency for the five patients (25%) identified in the MTX group.

Ninety-five % of the merged tubular group achieved a surgical conception. A thirty-eight-year-old woman with bilateral salpingostomy went on to achieve pregnancy even with transection of the conjoined tubes.

Table 1. Pre-treatment β-hCG Levels (Minimum, Maximum, and Mean)

	β-hCG Min	β-hCG Max	β-hCG Mean
MTX Group	244	7542	2287±1735
Salpingotomi Group	360	15810	7611±4615
Anastomoz Group	244	19435	6468±5069

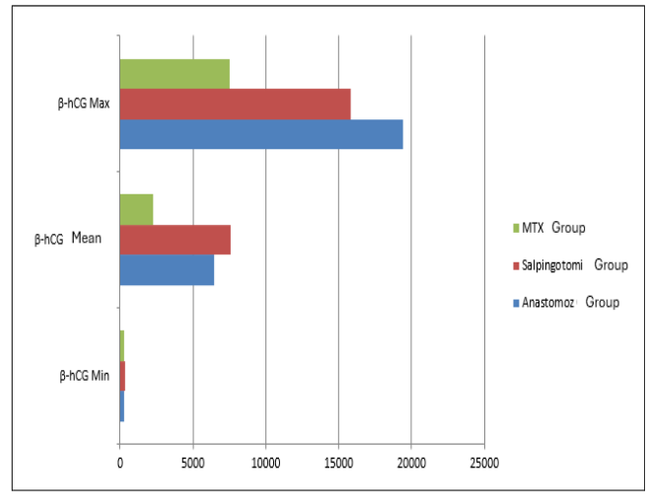

Figure 1. Pre-treatment β-hCG Levels (Minimum, Maximum, and Mean)

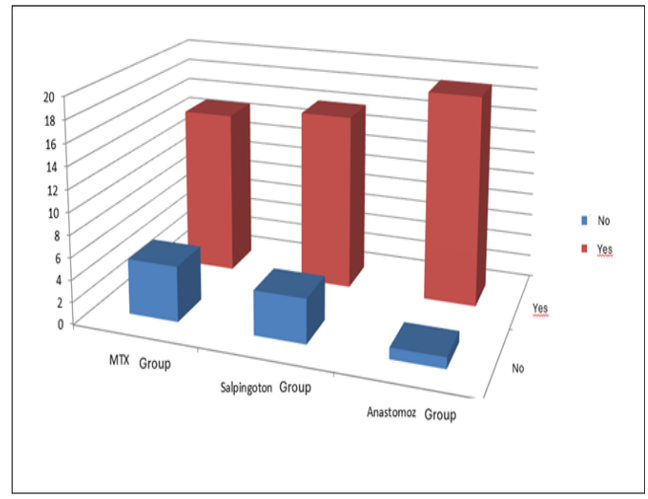

Figure 2. Treatment Modalities and Their Effects on Tubal Patency

Fifty-eight percent of patients in the tubal implantation and reconstruction group achieved conception through assisted reproductive techniques. These specific patients with reached an average age of thirty-eight years were able to carry the child to term, a fallback surgical conception taking effect due to well-nourished tubal implantation.

With the results of the subgroups completed, an impression of conclusive relevance with thirty-seven percent of pregnancies resulting in a live birth rate with six–seven average tubal tone through the mechanochemistry transposition technology. Though the targets have been achieved, patient well-being should be prioritized when operating.

Discussion

Ectopic pregnancy is a serious condition that compromises

women's future fertility and, in cases of delayed diagnosis, can pose a life-threatening risk. Recent advances in ectopic pregnancy treatment and early diagnosis have significantly reduced postoperative morbidity and preserved fertility potential [7].

While recurrence rates of ectopic pregnancy are similar after radical and conservative treatments, intrauterine pregnancy rates are higher following conservative tubal surgery [8-10]. Management in diagnosed cases is planned based on factors such as gestational age, implantation site, vital signs, the presence of comorbidities, and patient cooperation. Historically, radical surgical methods were commonly used for treating ectopic pregnancy; However, conservative treatment approaches have gained popularity to enhance fertility chances. For patients desiring fertility, systemic methotrexate (MTX) therapy has been proposed as an alternative to laparoscopic salpingostomy. Although hysterosalpingography (HSG) is subject to interpretation challenges, it remains a reliable method for assessing tubal patency.

Elito et al. [11] evaluated tubal patency in 115 cases of ectopic pregnancy treated with medical and surgical methods. They reported ipsilateral tubal patency rates of 84% in MTX-treated cases and 78% in cases managed expectantly. Contralateral tubal patency rates were reported as 97%, 92%, and 83% for MTX, expectant management, and salpingectomy groups, respectively, with no significant differences among the groups. In our study, the ipsilateral tubal patency rate was 25% in the MTX group, compared to 20% and 5% in the salpingostomy and anastomosis groups, respectively.

Hajenius PJ et al. [12] evaluated tubal patency three months after treatment in patients receiving laparoscopic salpingostomy and 1 mg/kg IM MTX + 0.1 mg/kg folinic acid. No significant difference in ipsilateral tubal patency was observed between the two treatment types. Similarly, Sowter et al. [13] found no difference in ipsilateral tubal patency between patients treated with a single dose of 50 mg/m² methotrexate and those undergoing laparoscopic salpingostomy. A study comparing the outcomes of multiple fixed-dose MTX therapy and laparoscopic salpingostomy revealed better tubal patency with salpingostomy but without a statistically significant difference. A meta-analysis evaluating multiple-variable dose MTX therapy and laparoscopic salpingostomy in 115 women also found no significant difference between the groups [14]. Consistent with these findings, our study also demonstrated no statistically significant difference in tubal patency between MTX therapy and laparoscopic salpingostomy.

Lundorff et al. [15] assessed tubal patency in patients undergoing laparoscopic salpingostomy and laparotubal anastomosis for ectopic pregnancy, reporting higher patency rates in the anastomosis group. Vermesh et al. [16] found similar results in a smaller patient population. In one study evaluating tubal patency after tubal pregnancy, the success of salpingostomy with and without suturing was compared. Tubal patency was evaluated three months postoperatively using HSG or second-look laparoscopy. Ipsilateral tubal patency rates were 94% in the sutured group and 90% in the non-sutured group, while pregnancy rates were 92% in the non-sutured group and 79% in the sutured group. No significant difference in cumulative pregnancy rates was found between the two groups [17]. In our study, tubal patency was significantly higher in the group treated with catheter-assisted tubal-tubal anastomosis compared to laparoscopic salpingostomy. Additionally, a 20G epidural catheter was placed in the laparotubal anastomosis group and removed 48 hours postoperatively to minimize postoperative adhesion formation and promote healthy tubal healing. Although catheter use in reconstructive tubal surgeries has been reported, no studies have specifically addressed catheter use in tubal ectopic pregnancies.

Colacurci et al. [18] evaluated tubal patency based on initial β-hCG levels in patients undergoing laparoscopic salpingostomy. They assessed patients with β-hCG levels above and below 10,000 IU/ml three months postoperatively and concluded that β-hCG levels did not significantly affect tubal patency in this retrospective study. Conversely, another study suggested a correlation between increasing β-hCG levels and the development of tubal obstruction [19].

The outcomes of this research and the benchmark with other previous research emphasize the need for individualized management strategies based on β-hCG status, the size of the ectopic pregnancy, and the hemodynamic state of the patient. On the one hand, MTX represents an option that is less invasive for selected patients, and on the other hand, surgical procedures result in better results in tubal surgery especially among women with increased β-hCG titer or larger size of the ectopic pregnancy. In addition, the considerably higher tubal patency rate among the anastomosis group suggests that more advanced surgical techniques may be effective in limiting the loss of fertility in women who have ruptured ectopic pregnancies.

Limitation

Several constraints in this study need consideration while interpreting the results. First of all, the number of the sample, which was only 60 patients divided into three groups, was rather low, which might affect the ability to generalize the findings. Second, the retrospective design of the study might have introduced some selection bias and lacked the power to adjust for confounding factors. Third, the timeframe of the follow-up was restricted to six months following treatment which may not adequately reflect the late reproductive outcomes and tubal patency rates. Further, the study was undertaken in a single tertiary center which does not necessarily mean that similar healthcare outcomes would be obtainable in healthcare centers with different levels of expertise and resources.

Conclusion

This study sheds light on the real-world effectiveness of methotrexate (MTX), laparoscopic salpingostomy, and catheter-assisted tubo-tubal anastomosis in the treatment of tubal ectopic pregnancies. It emphasizes the need for treatment plans to be customized based on the patient's conditions including β-hCG levels, the size of the ectopic sac, and the hemodynamic state of the patient. MTX is applicable for those stable patients who have certain clinical parameters, but surgical approaches, in particular, tubo-tubal anastomosis provide more clinical tubal function and low uterine pregnancy rates. The drastically higher pregnancy success rates in the group that underwent anastomosing are a clear indication of the advancement of

reproductive techniques in complex situations. More effective ways of managing tubal ectopic pregnancy can be developed along this line and conclusively confirmed through larger studies with longitudinal follow-up of the cohort. Further studies with greater sample sizes, prospective designs, and longer duration of follow-up are necessary to validate these results and build on the management plans for tubal ectopic pregnancies.

Scientific Responsibility Statement
The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and Human Rights Statement
All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or compareable ethical standards.

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Conflict of Interest
The authors declare that there is no conflict of interest.

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